

109TH CONGRESS
2D SESSION

H. R. 5975

To require the Agency for Healthcare Research and Quality, in consultation with the Director of the National Institutes of Health, to conduct research to develop valid scientific evidence regarding comparative clinical effectiveness, outcomes, and appropriateness of prescription drugs, medical devices, and procedures, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JULY 28, 2006

Mr. ALLEN (for himself, Mrs. EMERSON, Mr. WAXMAN, Mr. EHLERS, Mr. BERRY, Mr. BURTON of Indiana, Mr. BROWN of Ohio, and Mr. GUTKNECHT) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To require the Agency for Healthcare Research and Quality, in consultation with the Director of the National Institutes of Health, to conduct research to develop valid scientific evidence regarding comparative clinical effectiveness, outcomes, and appropriateness of prescription drugs, medical devices, and procedures, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Prescription Drug
3 Comparative Effectiveness Act of 2006”.

4 **SEC. 2. RESEARCH AND STUDY ON EFFECTIVENESS OF**
5 **CERTAIN PRESCRIPTION DRUGS.**

6 (a) IN GENERAL.—

7 (1) RESEARCH.—The Director of the Agency
8 for Healthcare Research and Quality, in consultation
9 with the Director of the National Institutes of
10 Health, shall conduct or support research, which
11 may include clinical research, to develop valid sci-
12 entific evidence regarding comparative clinical effec-
13 tiveness, outcomes, and appropriateness of prescrip-
14 tion drugs, medical devices, and procedures. In con-
15 ducting or supporting such research, particular con-
16 sideration shall be given to treatments that involve
17 high volume, high cost, or high risk to patients.

18 (2) SYSTEMATIC REVIEWS.—

19 (A) IN GENERAL.—The Director of the
20 Agency for Healthcare Research and Quality
21 shall conduct or support systematic reviews of
22 existing evidence regarding comparative clinical
23 effectiveness, outcomes, and appropriateness of
24 prescription drugs, medical devices, and proce-
25 dures. In conducting or supporting such re-
26 views, particular consideration shall be given to

1 treatments that involve high volume, high cost,
2 or high risk to patients.

3 (B) BETTER CLINICIAN AND PATIENT IN-
4 FORMATION ON SAFETY.—Within 12 months of
5 the date of the enactment of this Act, the Sec-
6 retary of Health and Human Services, in con-
7 sultation with the Director of the Agency for
8 Healthcare Research and Quality, the Commis-
9 sioner of Food and Drugs, and the Director of
10 the National Institutes of Health, shall develop
11 a coordinated plan for research on the most ap-
12 propriate methods for measuring and com-
13 paring adverse events associated with pharma-
14 ceuticals and other medical and surgical treat-
15 ments so that clinicians and patients can evalu-
16 ate the comparative safety as well as the com-
17 parative clinical effectiveness of the alternative
18 treatment options.

19 (b) ANNUAL REPORT.—Each year the Director of the
20 Agency for Healthcare Research and Quality shall prepare
21 a report on the results of the research, studies, and anal-
22 yses conducted under this section and submit the report
23 to the following:

24 (1) The Congress.

25 (2) The Secretary of Defense.

1 (3) The Secretary of Health and Human Serv-
2 ices.

3 (4) The Secretary of Veterans Affairs.

4 (5) The Administrator of the Centers for Medi-
5 care & Medicaid Services.

6 (6) The Director of the Indian Health Service.

7 (7) The Director of the National Institutes of
8 Health.

9 (8) The Director of the Office of Personnel
10 Management.

11 (c) REPORTS FOR PRACTITIONERS.—As soon as pos-
12 sible, but not later than a year after the completion of
13 any systemic review conducted pursuant to subsection
14 (a)(2), the Director of the Agency for Healthcare Re-
15 search and Quality shall—

16 (1) prepare a report on the results of such sys-
17 temic review for the purpose of informing health
18 care practitioners; and

19 (2) identify treatment options for which com-
20 parative clinical effectiveness judgments could not be
21 reached due to insufficient evidence and make such
22 identifications available to the Director of the Na-
23 tional Institutes of Health and other entities funding
24 research.

1 (d) INFORMATION FOR PATIENTS.—The Director of
2 the Agency for Healthcare Research and Quality shall cre-
3 ate a version of each report prepared for practitioners
4 under subsection (c)(1) in a form that is easily understood
5 by the individuals receiving the treatments involved.

6 (e) AVAILABILITY.—The Director of the Agency for
7 Healthcare Research and Quality—

8 (1) shall publish on the Agency’s Internet site,
9 and through other means that will facilitate access
10 by practitioners, each report prepared under sub-
11 section (b), (c), or (d); and

12 (2) make the information in such reports avail-
13 able to the public through easily accessible and
14 searchable electronic mechanisms, and in hard copy
15 formats as appropriate.

16 (f) ACCOUNTABILITY.—In carrying out this sub-
17 section, the Secretary of Health and Human Services shall
18 implement activities in a manner that makes publicly
19 available all scientific evidence relied upon and the meth-
20 odologies employed, provided such evidence and method
21 are not protected from public disclosure by section 1905
22 of title 18, United States Code, or other applicable law,
23 so that the results of the research, analyses, or syntheses
24 involved can be evaluated and replicated.

1 (g) AUTHORIZATION OF APPROPRIATIONS.—To carry
2 out this section, there are authorized to be appropriated
3 to the Agency for Healthcare Research and Quality and
4 the National Institutes of Health \$100,000,000 for fiscal
5 year 2007 and such sums as may be necessary for fiscal
6 year 2008 and each subsequent fiscal year.

